DSJ1&2-PR Exh 533

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov

Washington, D.C. 20537

February 7, 2007

Dear Sir or Madam:

This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.

Background

As each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country.[1] DEA has an obligation to combat this problem as one of the agency's core functions is to prevent the diversion of controlled substances into illicit channels. Congress assigned DEA to carry out this function through enforcement of the Controlled Substances Act (CSA) and DEA regulations that implement the Act.

The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion. Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[2]

The Statutory Scheme and Legal Duties of Distributors as DEA Registrants

Although most distributors are already well aware of the following legal principles, they are reiterated here as additional background for this discussion.

The CSA uses the concept of registration as the primary means by which manufacturers, distributors, and practitioners are given legal authority to handle controlled substances. Registration also serves as the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations, as Congress gave DEA authority under the Act to revoke and suspend registrations for failure to comply with these requirements. (Depending on the circumstances, failure to comply with the regulatory requirements might also provide the basis for criminal or civil action under the CSA.)

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[1] See National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised Au available at www.drugabuse.gov/PDF/RRPrescription.pdf

[2] 21 U.S.C. 801(2)

Before taking an action to revoke a registration, DEA must serve the registrant an order to show cause, which advises the registrant of its right to an administrative hearing before the agency (21 U.S.C. 824(c)). The CSA also gives DEA discretionary authority to suspend any registration simultaneously with the initiation of revocation proceedings in cases where the agency finds there is an imminent danger to the public health and safety (21 U.S.C. 824(d)).

DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.

The statutory factors DEA must consider in deciding whether to revoke a distributor's registration are set forth in 21 U.S.C. 823(e). Listed first among these factors is the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors must comply with applicable state and local law. Congress also gave DEA authority under this provision to revoke a registration based on the distributor's past experience in the distribution of controlled substances and based on "such other factors as may be relevant to and consistent with the public health and safety."

The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

It bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.

Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

In addition, distributors are required to file reports of distributions of certain controlled substances to the DEA ARCOS Unit, in the time and manner specified in the regulations (21 C.F.R. 1304.33). The failure to file ARCOS reports in a complete and timely manner is a potential statutory basis for revocation under section 823(e). Depending on the circumstances, the failure to keep or furnish required records might also be the basis for civil fines or criminal penalties under the CSA, as provided in 21 U.S.C. 842.

Circumstances That Might Be Indicative of Diversion

DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g., ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs
4. Ordering the same controlled substance from multiple distributors.

A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:

1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
8. Does the pharmacy offer to sell controlled substances without a prescription?
9. Does the pharmacy charge reasonable prices for controlled substances?
10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

Appeal No. 11-CS-003 (03/05/2007)

We look forward to continuing to work in cooperation with distributors toward our mutual goal of preventing the diversion of pharmaceutical controlled substances.

Sincerely,

Joseph T Rannazzisi

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

Appendix H / CS-003/03/05/2007)